

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K031501

B. Analyte: Whole Blood Glucose

C. Type of Test: Quantitative, utilizing Glucose Oxidase technology.

D. Applicant: American HealthCare, Inc.

E. Proprietary and Established Names: EASYGLUCO™ Monitoring System

F. Regulatory Information:

1. Regulation section:

21 CFR 862.1345 Glucose Test System

2. Classification:

Class II

3. Product Code:

NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose

JJX, Single (Specified) Analyte Controls (Assayed and Unassayed) Class I

4. Panel:

Chemistry (75)

G. Intended Use:

1. Indication(s) for use:

The EASYGLUCO™ Monitoring System is used by individuals with diabetes. It is for the quantitative measurement of glucose levels in whole blood, as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings.

2. Special condition for use statement(s):

Provides plasma equivalent results.

3. Special instrument Requirements:

N/A

H. Device Description:

The EASYGLUCO™ Monitoring System consists of the EASYGLUCO meter, EASYGLUCO Test Strips, Auto-Lancet Device, Infopia Check Strip, Greenlan Lancets, and Control Solution.

I. Substantial Equivalence Information:1. Predicate device name(s):

LifeScan, Inc. One Touch ® Ultra ®

2. Predicate K number(s):

K024194

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	EASYGLUCO™	ONE TOUCH® Ultra®
Detection method	Amperometry: current is generated by oxidation of reduced mediator.	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode

Differences		
Item	Device	Predicate
	EASYGLUCO™	ONE TOUCH® ULTRA®
Test range	10 – 600 mg/dL	20 – 600 mg/ dL
Hematocrit Range	30 – 55%	30 – 55%
Test Time	9 seconds	5 seconds
Sample Volume	3 uL	1 uL
Temperature & Humidity range	50 - 95° F 10 - 35° C 10 – 90%	43 - 111° F 6 - 44° C 10 - 90%
Open use time	3 months	3 months
Coding	Button (C1 – C40)	Button (C1 – C49)

Memory capability	From 7 to 90-day average and 200 tests in the memory	14-day average and last 150 tests in the memory
Power	3v Li battery (CR2032)	3V Li battery (CR2032)
Battery life	Running 5,000 test	Running 1,000 test
Size: LxWxH (mm)	55x91x22	79x57x21
Weight	55g (with battery)	42g (with battery)
Warranty	3 years	3 years
Software	EASYGLUCO™ diabetes management software	IN TOUCH® diabetes management software

J. Standard/Guidance Document Referenced (if applicable):

NCCLS EP-7

K. Test Principle:

Electrochemical biosensor technology is used with glucose oxidase. The principle of the test relies upon a specific type of glucose in the blood sample, the dehydrogenase glucose that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Testing was conducted by taking 4 mL of blood that was treated with EDTA through a vacuum tube. Glucose was added to the 4 mL of blood to generate 5 different levels of glucose concentration for the test. Each of the samples was measured 5 times. Below are the glucose concentration ranges for each level that were measured. (See Table I for Summary of Test Results)

<i>Level</i>	<i>Glucose Concentration Range</i>
<i>1</i>	<i>30 – 50 mg/dL</i>
<i>2</i>	<i>51 – 110 mg/dL</i>
<i>3</i>	<i>111 – 150 mg/dL</i>
<i>4</i>	<i>151 – 250 mg/dL</i>
<i>5</i>	<i>251 – 400 mg/dL</i>

Three control solutions of Low, Normal and High were prepared. Each of the controls was measured twice a day, once in the morning and once in the afternoon for a month.

(Table I (below) shows a summary of the Within-Run Precision and the Day-to-Day Precision Tests.)

Table I: Summary of Test Results

Within-Run Precision

Control Samples	No. Of Assay	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	5	47.2	1.6	3.5
Level 2	5	94.2	2.3	2.4
Level 3	5	131	4.5	3.4
Level 4	5	221	6.0	2.7
Level 5	5	339.8	7.4	2.2

Day-to-Day Precision

Control Samples	No. Of Assay	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low	80	74.2	2.8	3.7
Normal	80	128.8	6.2	4.8
High	80	252.9	9.9	3.9

b. Linearity/assay reportable range:

A blood sample of 25 mL was taken, treated with EDTA vacuum tube, to be set for a day. Two glucose concentrations of 10 mL (high and low concentrations) were prepared. Each of the glucose levels was measured 5 times to test for precision. The glucose linearity dilution study demonstrated the following regression:

$$Y = 62.553x - 30.078 \quad R^2 = 0.9991$$

c. Traceability (controls, calibrators, or method):

CAS# (Chemical Abstract Service)

MDL# (MDL, inc. formerly Molecular Design Laboratories)

Glucose # 492615 SigmaUltra MFCD00063989

Traceability referenced to NBS, NIST Standards

d. Detection limit:

10 – 600 mg/dL

0.6 – 33.3 mmol/L

e. Analytical specificity:

Interference testing was conducted to determine the effect of select endogenous and exogenous substances. A series of test samples, systematically varying in the concentration of the interferents, was prepared by making quantitative, volumetric mixtures of two pools: one at the highest concentration to be tested and the other at the lowest. The substances and concentrations of the interferents are recommended at NCCLS EP7-P.

f. Assay cut-off:
N/A

2. Comparison studies:

a. Method comparison with predicate device:

The accuracy of the EASYGLUCO™ System was assessed by comparing blood glucose results obtained by patients with those obtained using the Hitachi 747 Chemistry Analyzer. Glucose levels were measured on 416 blood samples, and 104 fresh capillary blood specimens by 104 diabetic patients and three healthcare professionals at three different clinical centers.

A direct correlation between The Hitachi 747 and EASYGLUCO™ were confirmed in the 416 blood samples. Results obtained by Healthcare Professionals in Clinical Centers presented the following regression:

Slope =	0.957
y- intercept	5.4
Correlation coefficient (r)	0.979
No. of samples	416
Range tested	68 – 430 mg/dL

The Linear regression of the 104 diabetic patients – Hitachi 747 vs. EASYGLUCO™ System presented the following regression:

Slope =	0.957
y- intercept	12.1
Correlation coefficient (r)	0.978
No. of samples	104
Range tested	81 – 425 mg/dL

b. Matrix comparison:
N/A

3. Clinical studies:

a. Clinical sensitivity:
N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Expected blood glucose levels for people **without** diabetes:

<u>Time</u>	<u>Range (mg/dL)</u>	<u>Range (mmol/L)</u>
Before Breakfast:	70 – 105	3.9 – 5.8
Before Lunch or Dinner:	70 – 110	3.9 – 6.1
1 hour after meals:	less than 160	less than 8.9
2 hours after meals:	less than 120	less than 6.7
Between 2 and 4 AM	Greater than 70	Greater than 3.9

- referenced from Joslin Diabetes Manual

M. Conclusion:

Based upon review of the information and labeling provided, this device is Substantially Equivalent to 21 CFR 862.1345, 75 NBW, System, Test, Blood Glucose, Over the Counter and 75 CGA Glucose Oxidase, Glucose